REMARKS

Claims 1-9 are pending. Claims 1, 2, and 4 have been canceled. Claims 3, 6, and 7 have been amended. Support for the amendments is found, for example page 29, lines 8-12. As such, no new matter has been introduced by way of these amendments. Reconsideration of the pending claims is respectfully requested.

The Pending Claims are Useful

The pending claims stands rejected under 35 U.S.C. § 101 because the claimed invention allegedly is not supported by either a specific or substantial asserted utility or a well established utility. Applicants disagree. The specification clearly contemplates the use of the disclosed nucleic acid sequences for diagnostic purposes, for example, to diagnose a cardiac disease by detecting the differential expression of a polynucleotide comprising SEQ ID NO: 2 or the coding region of SEQ ID NO: 2 that encodes SEQ ID NO: 1.

The case law requires a reasonable correlation between the activity of the claimed subject matter and the asserted utility. *See Cross v. Iizuka*, 224 USPQ 739, 747 (Fed. Cir. 1985). Here, the claimed array is useful, for example, as a diagnostic agent to diagnose a cardiac disease state such as myocardial infarction, cardiac hypertrophy, and viral myocarditis, by indicating the differential expression of a polynucleotide comprising SEQ ID NO: 2. This asserted utility is sufficiently specific to satisfy the utility requirement as it relates to specific diseases and not to any disease state in the abstract.

Support for this asserted utility can be found throughout the specification. For example, the specification discloses the use of the nucleotide sequences to "enable the analysis of cell, tissue, or peripheral blood samples." Page 42, lines 20-21. This analysis can be used to diagnose a cardiac disease by detecting the differential expression of the claimed sequence. See page 41, lines 27-30.

Differential expression of the claimed sequence was reasonably correlated to three specific cardiac diseases, myocardial infarction, cardiac hypertrophy, and viral myocarditis. In an *in vivo* myocardial infarction model, the claimed sequence was down-regulated by about 2-fold at the two week time point and about 1.8-fold at the sixteen week time point. In an *in vivo* cardiac hypertrophy model, the claimed sequence was down-regulate by about 2.5-fold at the ten week time

point. Interestingly, the claimed sequence was found to have been up regulated by about 2-fold at the nine day time point. Similarly, expression levels of the claimed sequence were found to have been up regulated in an *in vitro* cardiac hypertrophy model. Because the present specification discloses a correlation among differential expression levels of SEQ ID NO: 2 with a variety of cardiac disease states, Applicants submit that the claimed subject matter is supported by a specific utility.

The claimed subject matter is also supported by a substantial utility. Specifically, the claimed subject matter has a substantial utility in diagnosing various cardiac disease states, such as myocardial infarction, cardiac hypertrophy, and viral myocarditis. Because diagnosis of cardiac disease is a substantial utility, as opposed to mere experimentation, Applicants have asserted a substantial or real-world use for the claimed invention.

Applicants submit that one of ordinary skill in the relevant art would have known by reading the disclosure of the present application that the claimed subject matter had utility as a diagnostic reagent for detecting conditions related to cardiac diseases such as myocardial infarction, cardiac hypertrophy, and viral myocarditis. As such, Applicants request that the present rejection of the pending claims be withdrawn.

The Pending Claims are Supported by an Enabling Specification

The pending claims were also rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement, primarily as a companion rejection to the alleged lack of utility rejection discusses above. Because the claimed subject matter is useful, the present enablement rejection falls away and should be withdrawn.

The Examiner took issue with other aspects of the claims, particularly with the claim terms "reference" and "complementary." The array claim language has been clarified to more distinctly recite the subject matter of the invention. By doing so, Applicants have further overcome the basis for the present rejection.

The test for enablement is not whether some experimentation is required to practice an invention but whether an undue amount of experimentation is required. Here, one of ordinary skill in the art would be aware of the techniques necessary to use the claimed subject matter as a

diagnostic reagent. For example, if a skilled artisan desired to assay a patient for the presence of a cardiac disease such as infarction, hypertrophy, or viral myocarditis, the skilled artisan would obtain a cardiac biopsy and determine the expression level of the claimed sequence. Methods for performing endomyocardial biopsies are well known in the art. For example, see Mason, *et al.*, "Clinical merit of endomyocardial biopsy," *Circulation*, 79:971-979 (1989). Methods for determining expression levels of the claimed sequence are also well known in the art and discussed in the present specification. Once the expression level of the claimed sequence is determined to be either up or down regulated, a clinician could conclude that the subject was indeed suffering from a cardiac disease.

The Examiner argued in the Office Action that further experimentation would be required to use the claimed subject matter. Applicants disagree. The claimed subject matter is directed to determining expression levels in a patient is suffering from a cardiac disease such as infarction, hypertrophy, or viral myocarditis, a renal disease, or an inflammatory disease. Using the array would not require undue experimentation. Applicants submit that this information is useful in and of itself. Thus, based on the teachings of the specification and knowledge held by those of ordinary skill in the relevant art, the claimed subject matter can be practiced by one of ordinary skill in the art without undue experimentation.

In light of the remarks provided above, Applicants submit that the subject matter of the pending claim is fully supported by an enabling disclosure. As such, Applicants request withdrawal of the present rejection.

The Pending Claims are Supported by an Adequate Written Description

The pending claims were also rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the written description requirement. Specifically, the Examiner took issue with the claim terms "reference" and "complementary." These terms no longer appear in the claims. Moreover, the recited array contains a probe of 20 to 80 bases of SEQ ID NO:2. There is literal support for this subject matter in the specification. As such, Applicants were clearly in possession of the claimed subject matter at the time the application was filed. Therefore, the present rejection should be withdrawn.

Claims 3 and 5-9 are Definite

The pending claims were also rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Examiner took issue with the claim terms "reference," "e.g.," in claim 3 and the phrase "further mammalian homologue" in claim 6(e). These terms no longer appear in the claims. Therefore, the present rejection should be withdrawn.

Claims 3, 5 and 6 are Novel over Fodor

Claims 3, 5, and 6 stand rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by Fodor (U.S. Pub. No. 2001/0053519) and separately under 35 U.S.C. § 102(b) by Brennan (U.S. Patent No. 5,474,796). According to the Examiner, the Fodor reference teaches "an array comprising every 10 oligonucleotide (see Example 2)." Office Action, page 18. While the application says that it teaches the 1,048,576 possible ten-mers, if does not actually disclose these peptides, and as such does not provide sufficient written description to support an anticipation rejection. Similarly, while Brennan states that every permutation of 10-mer was made, they do not disclose the sequences in question, and it does not disclose the actual chemical structures of those oligonucleotides.

Nevertheless, claim 3 recites the use of oligonucleotides with 20-80 bases. This feature of the claims further serves to distinguish the pending claims from the cited art. Because these reference does not teach all the limitations of the pending claims, they are not an anticipatory reference and the present rejections should be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 219002031710. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 7, 2007

Respectfully submitted,

By: /James J. Mullen, III/
James J. Mullen III, Ph.D.
Registration No.: 44,957
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
(858) 720-7940